

## ABSTRACT

Methods and kits for used as an internal or external control in rare cell analysis are disclosed. A plurality of fluorescently distinct sets of cells is used to define a range to assess the isolation of rare target cells from a sample. Thus, a known number of cells, expressing the surface and intracellular antigens present in the targeted rare cells, are stabilized and modified in such a way that they can be discriminated from the targeted rare cells. In addition, these cells are separated into at least two sets based upon the number. These sets are detectably distinct from each other and provide an upper and lower indication of the detection ability of the rare cell assay.